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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,615	08/22/2003	William J. Hennen	2820-5474.1US	8609

24247 7590 03/20/2007

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EXAMINER	
KIM, TAEYOON	
ART UNIT	PAPER NUMBER
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,615	HENNEN, WILLIAM J.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-18,50 and 53-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-18,50 and 53-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1,4-18,50 and 53-78 are pending.

Response to Amendment

Applicant's amendment and response filed on Dec. 26, 2006 has been received and entered into the case.

Claims 2, 3, 19-49, 51 and 52 are canceled, claims 1,4-18,50 and 53-78 are pending and have been considered on the merits. All arguments have been fully considered.

The rejections made to claims 1-3, 7, 8, 10-15, 50-52, 56, 57 and 59-64 under 35 U.S.C. §102(e) have been withdrawn due to the amendment.

The rejections made to claims 4-6, 9, 16-18, 53-55, 58 and 65-67 under 35 U.S.C. §103(a) have been withdrawn due to the amendment.

Claim Objections

Claims 68 and 75 are objected to because of the following informalities: the articles in front of arginine and lysine appear to be inappropriate, unless the composition contains a single molecule of arginine or lysine. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-18, 50, 53-67 and 69-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4-18, 50, 53-67, 71 and 73 disclose a paragraph "pathogen associated with". It is not clear what the paragraph points out to claim. It can be interpreted that a pathogen is a direct cause of a cardiovascular disorder, or any indirect, secondary or tertiary effect of pathogen may be related to cardiovascular disorder. It has been interpreted as broadest possible to encompass any pathogen which will trigger host immune response and inflammation, and therefore contribute to the atherosclerotic process, leading to cardiovascular disorder.

The term "treated" in claims 1 and 50, and their dependents does not clearly point out what the term is intended to claim. It is not clear whether the cardiovascular disorder has been treated with a composition comprising transfer factor, the disorder treated with any other means prior to the use of the composition, or the disorder which will be treated with the composition.

Claims 69, 77 and 78 are drawn to the limitations to arginine and lysine comprising magnesium arginate and magnesium lysinate, respectively. It is well known in the art that arginine and lysine are the single amino acids and not compositions comprising magnesium arginate or magnesium lysinate, respectively. Therefore, it is not clear what the limitation of the claims intends to point out. The claims can be interpreted that the arginine or lysine in the composition is derived from magnesium arginate or magnesium lysinate, respectively, or magnesium arginate and magnesium lysinate are in the composition. For the examination, the claims are interpreted as arginine and lysine are derived from magnesium arginate and magnesium lysinate, respectively.

Claim 69 recites the limitation "lysing" in third line. There is insufficient antecedent basis for this limitation in the claim. It appears that the term would be "lysine" and the claim has been examined with the term "lysine".

The term "amount" in claim 70 is not clear because there is no disclosure whether the amount in volume or weight, etc.

The term "substantially" in claims 70 and 72 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "a first amount" in claim 72 is not clear what the term intends to point out in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific antigen of pathogen, which does not mimic host cellular components, does not reasonably provide enablement for each and every antigen of each and every pathogen (especially those mimic host cellular components). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The claims are drawn to transfer factor specific for "any" antigen of "any" pathogen. It is generally believed that there are non-specific as well as specific transfer factor. However, the claims are too broad to encompass any antigen (protein, lipid, etc.) of any pathogen which may or may not effectively reduce or decrease the amount of inflammation in blood vessels. Thus, it is not predictable without further undue experimentation that a transfer factor specific for an antigen of a pathogen would provide the intended result of reducing inflammation caused by the pathogen. A person of ordinary skill in the art at the time of invention made therefore needs to test every and single transfer factor specific for a variety of different pathogens or a variety number of antigens of the pathogen to determine whether the specific transfer factor against an antigen from a pathogen has effective activity to reduce inflammation. It would require enormous amount of undue experimentation to identify transfer factor specific for antigen(s) of pathogens or a pathogen and also reduce the inflammation caused by the pathogen/antigen thereof.

Furthermore, Vercellotti (2001) teaches that there are antigens of pathogens which mimic the host cellular components, and thus triggering autoimmunity. As the applicant argued in the response filed on Dec. 26, 2006, transfer factor specific for the such antigens would eventually increase inflammation response rather than decreasing the inflammation caused by the pathogen, thus not enabling the limitation of "an inflammation-reducing component".

Claims 1, 4-18, 50, 53-67 and 70-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current application generically claims a composition comprising any transfer factor specific for any pathogen or for any antigen of any pathogen, however the specification does not contain an adequate description for the entire scope of this limitation and thus the claims. Moreover, the composition has a limitation that the pathogen being associated with a cardiovascular disorder. Although there

M.P.E.P. §2163 recites, "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient

to show the applicant was in possession of the claimed genus...when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. **For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.**"

Claim 70 discloses the limitation of transfer factor and Vitamin C being in equal amount. This limitation does not have an adequate support from the specification.

Claim 72 discloses the phrase "substantially a first amount" which does not have any support from the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7, 8, 10-15,17, 50, 56, 57, 59-64 and 66 are rejected under 35 U.S.C. 102(e) as being anticipated by Ramaekers (U.S. Patent 6,506,413 B1; filed on Apr. 30, 2001).

Claims 1, 7, 8, 10-15, 50, 56, 57, 59-64 and 68-78 are drawn to a composition for treating a cardiovascular disorder comprising an inflammation-reducing component for decreasing inflammation in blood vessels comprising transfer factor specific for a

pathogen or an antigen of a pathogen (claim 1), or a pathogen-reducing component for decreasing pathogens in blood vessels comprising transfer factor specific for a pathogen or an antigen of a pathogen (claim 50), with a blood flow-enhancing component (claims 1 and 50); being mammalian transfer factor (claims 7 and 56); the mammalian transfer factor comprising a colostrums extract (claims 8 and 57); the composition of claim 1 or claim 50 comprising an LDL receptor-binding component (claims 10 and 59); the LDL receptor-binding component comprising lysine or lysine salt (claims 11 and 60); the blood flow-enhancing component comprising arginine or nicotinamide (claims 12 and 61); the composition of claim 1 or claim 50 further comprising antioxidant (claims 13 and 62); the antioxidant being hydrophobic (claims 14 and 63); the hydrophobic antioxidant being vitamin E (claims 15 and 64); the composition further comprising a cholesterol-reducing element (claims 17 and 66); and the composition further comprising a fat oxidation prevention element (claims 18 and 67); a composition comprising transfer factor, vitamin C, niacinamide, arginine and lysine (claim 68); a limitation to the arginine and the lysine being derived from magnesium arginate and magnesium lysinate, respectively (claim 69); a limitation to the transfer factor of claim 68 being specific for a pathogen or an antigen of a pathogen (claim 71); a composition comprising transfer factor and Vitamin C (claim 72); a limitation to the transfer factor of claim 68 being specific for a pathogen or an antigen of a pathogen (claim 73); a limitation to the composition of claim 73 further comprising a LDL receptor-binding element, a blood flow-enhancing element, a blood cholesterol reducer (claim 74); a limitation to the LDL receptor-binding element comprising lysine,

the blood flow-enhancing element comprising arginine (claims 75 and 77); a limitation to the blood cholesterol reducer comprising niacinamide (claims 76 and 78).

Ramaekers teaches a composition containing mammalian transfer factor which would be antigen-specific (varicella antigen; column 1, lines 29-30) or pathogen-specific (herpes simplex virus; column 1, lines 21-22) (claims 1-3, 7, 50-52 and 56) from colostrums extract (claims 8 an 57), arginine or nicotinamide (niacinimide) (claims 12 and 61), lysine (claims 10, 11, 59 and 60), a hydrophobic antioxidant as well as a fat oxidation prevention element, vitamin E (claims 13-15, 18, 62-64 and 67) (see column 2; table 2), niacin (converted to niacinamide in vivo), a cholesterol-reducing element supported by (see column 2, line 65). Ramaekers also discloses Vitamin C in the composition comprising transfer factor (see column 5, lines 23-25).

Although Ramaekers do not specifically teach that lysine as a LDL receptor-binding component (claims 11, 60, 74 and 75), arginine being a blood flow-enhancing component (claim 10, 59, 74 and 75), niacin (niacinamide) being a cholesterol-reducing element (claims 17, 66, 74, 76 and 78), or vitamin E, a fat oxidation prevention element (claims 18 and 67), it is an inherent property of lysine/lysine salt, arginine, or niacin (niacinamide) having a property as a LDL receptor-binding component, a blood flow-enhancing component, or cholesterol-reducing element as supported by Rath et al. (U.S. Patent 5,650,418), Tentolouris et al. (Int. J. Cardiol., 2000,75(2-3):123-128), Cholesterol-lowering drugs (http://www.americanheart.org/presenter.jhtml?identifier=4510; page 2), or Focant et al. (J. Dairy Sci. 1998, 81:1095-1101, Abstract), respectively.

Although Ramaekers does not specifically teach the intended use of the composition for cardiovascular disorders, the composition of Ramaekers containing an inflammation-reducing component such as transfer factor, a blood flow enhancing component such as arginine and niacinimide, and a LDL receptor-binding agent such as lysine salt would inherently possess an ability to treat cardiovascular disorders as supported by Gordon (Explore, 1999, http://www.explorepub.com/articles/heart_disease.html, page 3), Kirkpatrick (J. Allergy and Clin. Immunol. 1975, 55(6):411-421; Abstract) and Tentolouris et al. (supra; Abstract), respectively.

Thus, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-6, 9, 16-18, 53-55, 58 and 65-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramaekers (supra) in view of Tokoro (U.S. Patent 5,080,895).

Claims 4-6 and 53-55 are drawn to limitations to the composition of claims 1 or 50 being nonmammalian (claims 4 and 53); being avian transfer factor (claims 5 and 54); the avian transfer factor comprising an egg extract (claims 6 and 55).

Ramaekers teaches a composition having transfer factor and arginine and/or nicotinamide (claims 1 and 2).

Ramaekers does not teach that the transfer factor is non-mammalian, avian nor from egg extract.

Tokoro teaches transfer factor from egg extract of immunized hen (see Examples).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to replace the mammalian transfer factor of Ramaekers with the transfer factor from egg extract taught by Tokoro.

The skilled artisan would have been motivated to make such a modification because the production of transfer factor (food factor) in a large amount from colostrums is difficult and limited due to its production is limited to a few days, and furthermore necessitates a vast farm land according to Tokoro (see column 1, lines 39-49).

The person of ordinary skill in the art would have had a reasonable expectation of success in replacing transfer factor of Ramaekers with that of Tokoro because the production of transfer factor and/or antibody from eggs of immunized hen has been successfully practiced in the art.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Claims 9 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramaekers (supra) in view of Kirkpatrick et al. (U.S. Patent 5,470,835; published on

Nov. 28, 1995) in further view of Vercellotti (Trans. Am. Clin. Climatol. Assoc. 2001, 112:215-222; Abstract).

Claims 9 and 58 are drawn to limitations to an inflammation-reducing component or a pathogen-reducing component in the composition of claim 1 or 50 being specific for HSV-II (claims 9 and 58).

Ramaekers teaches a composition having transfer factor as an inflammation-reducing component (claim 1) or a pathogen-reducing component (claim 50), and arginine and/or nicotinamide as a blood flow-enhancing component.

Ramaekers also teaches transfer factor is an effective therapeutic for Herpes simplex virus (HSV) (column 1, lines 21-22).

Ramaekers does not teach transfer factor being specific for HSV-II.

Kirkpatrick et al. teach transfer factor specific for HSV-II.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use transfer factor specific for HSV-II of Kirkpatrick et al. in the composition of Ramaekers.

The skilled artisan would have been motivated to make such a modification because since Vercellotti teaches that HSV-II infected individuals have the greatest relative risk for coronary artery disease (see Abstract), transfer factor specific for HSV-II would reduce the risk factor for coronary artery disease in human, hence even more beneficial in treating cardiovascular disorders.

The person of ordinary skill in the art would have had a reasonable expectation of success in using transfer factor specific for HSV-II in the composition of Ramaekers to treat cardiovascular disorders because transfer factor specific for HSV-II has been successfully generated by Ramaekers.

Claims 16 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramaekers (supra) in view of Singh et al. (J. Assoc. Physicians India, 1998 46(3):299-306; Abstract).

Claims 16 and 65 are drawn to limitations to the antioxidant comprising coenzyme Q10 (claims 16 and 65).

Although Ramaekers does not teach the use of coenzyme Q10 in the composition, it would have been obvious for the person of ordinary skill in the art at the time the invention was made to replace antioxidants such as vitamin E taught by Ramaekers with coenzyme Q10, another well-known antioxidant taught by Singh et al., for the same purpose.

Furthermore, the skilled artisan would have been motivated to make such a modification because Singh et al. teach Coenzyme Q10 deficiency in patients with congestive heart failure and coronary artery disease (see Abstract) and therefore providing a motivation to replace vitamin E with coenzyme Q10 which would be beneficial to cardiovascular disorders.

M.P.E.P. § 2144.06 states "*In re* Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958) (The mere fact that components are claimed as members of a Markush group

cannot be relied upon to establish the equivalency of these components. However, an applicant's expressed recognition of an art-recognized or obvious equivalent may be used to refute an argument that such equivalency does not exist.); *In re* Scott, 323 F.2d 1016, 139 USPQ 297 (CCPA 1963) (Claims were drawn to a hollow fiberglass shaft for archery and a process for the production thereof where the shaft differed from the prior art in the use of a paper tube as the core of the shaft as compared with the light wood or hardened foamed resin core of the prior art. The Board found the claimed invention would have been obvious, reasoning that the prior art foam core is the functional and mechanical equivalent of the claimed paper core. The court reversed, holding that components which are functionally or mechanically equivalent are not necessarily obvious in view of one another, and in this case, the use of a light wood or hardened foam resin core does not fairly suggest the use of a paper core.); Smith v. Hayashi, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.). An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramaekers (supra) in view of Pearson et al. (US 6,693,094).

Claim 69 is drawn to a limitation to the arginine and the lysine being derived from magnesium arginate and magnesium lysinate, respectively.

Ramaekers anticipates the limitation of the presence of arginine and lysine in the composition comprising transfer factor, vitamin C and niacinamide, and therefore renders obvious (see above).

Although Ramaekers does not teach the source of the arginine being magnesium arginate, since the key element of magnesium arginate is arginine, magnesium arginate is considered as art-recognized equivalent to arginine as evidenced by Pearson et al. Pearson et al. disclose that examples of L-arginine include L-arginine ascorbate, magnesium L-argniate, zine L-arginate and copper L-arginate and their bis-L-arginine and bis-ascorbate forms (see column 8, lines 38-41). Similarly, magnesium lysinate is considered as an art-recognized equivalent of lysine.

M.P.E.P. §2144.06 states "In re Scott, 323 F.2d 1016, 139 USPQ 297 (CCPA 1963) (Claims were drawn to a hollow fiberglass shaft for archery and a process for the production thereof where the shaft differed from the prior art in the use of a paper tube as the core of the shaft as compared with the light wood or hardened foamed resin core of the prior art. The Board found the claimed invention would have been obvious,

reasoning that the prior art foam core is the functional and mechanical equivalent of the claimed paper core. The court reversed, holding that components which are functionally or mechanically equivalent are not necessarily obvious in view of one another, and in this case, the use of a light wood or hardened foam resin core does not fairly suggest the use of a paper core.); Smith v. Hayashi, 209 USPQ 754 (Bd. of Pat. Inter. 1980) (The mere fact that phthalocyanine and selenium function as equivalent photoconductors in the claimed environment was not sufficient to establish that one would have been obvious over the other. However, there was evidence that both phthalocyanine and selenium were known photoconductors in the art of electrophotography. "This, in our view, presents strong evidence of obviousness in substituting one for the other in an electrophotographic environment as a photoconductor." 209 USPQ at 759.)."

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Response to Arguments

In the response filed on Dec. 26, 2006, applicant argued that Ramaekers' reference does not expressly or inherently describe a composition that includes both a blood flow-enhancing component and transfer factor specific for at least one pathogen (or an antigen thereof) associated with a treated cardiovascular disorder. This argument is found not persuasive because Ramaekers teaches all the limitation of the claimed invention. As discussed above, Ramaekers teaches a composition comprising transfer factor specific to a pathogen or an antigen thereof, a blood flow-enhancing component

such as arginine (see Table 2). The limitation to the transfer factor specific for a pathogen (or an antigen thereof) associated with a treated cardiovascular disorder has been interpreted that any pathogen (or an antigen thereof) causing inflammatory response has a potential risk of a cardiovascular disorder as taught by Vercellotti (2001). An infection caused by any pathogen would eventually develop inflammatory response. More specifically, the infection by herpes simplex virus as disclosed by Ramakers would induce inflammation as evidenced by Chang et al. (2000). Therefore, any transfer factor specific for a pathogen (or an antibody thereof) would satisfy the limitation.

Applicant argued against rejections under 35 U.S.C. §103(a) that Tokoro's transfer-like component is not transfer factor because it may cause a non-specific improvement in treated animal's immune system response, and is incapable of causing immune system of a treated animal to elicit a specific response (i.e., a response to a particular antigen). In other words, applicant argued that Tokoro's transfer factor-like component is different from "transfer factor" of the current application because it does not have specificity. The examiner respectfully disagrees with this argument because Tokoro specifically teaches "transfer factor-like" substance is obtained from a hen immunized against a selected antigen (specificity) such as pathogenic bacteria (see Abstract). Thus, the "transfer factor-like" component of Tokoro indeed has specificity against a specific antigen of pathogenic bacteria. Applicant referred a "transfer factor-like" substance of Collins et al. ('938), which is called as "unknown food factor", that it dose not have any specificity. However, the substance of Collins et al. is indeed

different from "transfer factor-like" component of Tokoro, and therefore the comparison to the substance of Tokoro with that of Collins et al. is moot.

In conclusion, since Tokoro's transfer factor-like component appears to be identical as transfer factor of the current invention because it has against a specific antigen of pathogen (bacteria) and therefore, the use of hen for the production of transfer factor against specific pathogen and/or antigen thereof would have been successfully carried out.

The argument on the reference by Hennen is moot because the rejection has been withdrawn.

Applicant argues that the rejection made by Ramaekers in view of Kirkpatrick et al. and in view of Vercellotti are allowable because claim 1 and claim 50 are allowable. Moreover, applicant argues that the reference of Vercellotti teaches away from the current invention because according to Vercellotti, transfer factor specific for an antigen, which mimics host cellular component, would nothing but increase inflammation via autoimmune response. The examiner agrees with this assertion and because of such limitation, the current invention (claims 1 and 50) is not enabled for such transfer factor having specificity against host cellular components as discussed above. Nonetheless, Ramaekers teaches all the limitations of independent claims (claims 1 and 50), and Kirkpatrick et al. teach transfer factor against HSV-II. The teaching of Vercellotti provides a motivation to replace the transfer factor of Ramaekers with the transfer factor of Kirkpatrick et al., rather than provide any structural limitations to the composition of Ramaekers and Kirkpatrick et al. The motivation given by Vercellotti is based on that

HSV-II infected individuals have the greatest relative risk of coronary artery disease, and therefore, the use of transfer factor specific for HSV-II would be beneficial in treating cardiovascular disorders caused by HSV-II infection.

Finally, applicant argues that none of references describes or teaches a composition comprising transfer factor, vitamin C, niacinamide, arginine, and lysine of the new claims (claims 68-78). This is not persuasive because Raemaekers teaches all the limitations of the claims as discussed above (see Table 2 of Raemaekers).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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